

CLAIMS

What is claimed is:

1. A self-expanding hearing device comprising:  
a body,  
a membrane coupled to said body; and,  
a frame coupled to said body, said frame being constructed so that a user can compress said frame for insertion into the user's ear canal and when the user releases compression the frame expands.
2. A self-expanding hearing device according to Claim 1 wherein said body includes a microphone and a speaker.
3. A self-expanding hearing device according to Claim 2 wherein said body is flexible.
4. A self-expanding hearing device according to Claim 3 wherein said body comprises a flexible spring.
5. A self-expanding hearing device according to Claim 3 wherein said body comprises a flexible Nitinol tube.

6. A self-expanding hearing device according to Claim 5 wherein said flexible body is a flexible Nitinol tube with slits.
7. A self-expanding hearing device according to Claim 2 wherein said body is formable by a user.
8. A self-expanding hearing device according to Claim 2 wherein said body is shaped to conform the ear canal.
9. A self-expanding hearing device according to Claim 1 wherein said body is asymmetrically located with respect to said frame.
10. A self-expanding hearing device according to Claim 1 wherein said frame includes a plurality of supports.
11. A self-expanding hearing device according to Claim 10 wherein said supports are elastic.
12. A self-expanding hearing device according to Claim 10 wherein said supports are formed of a superelastic material.
13. A self-expanding hearing device according to Claim 12 wherein said superelastic material is Nitinol.

14. A self-expanding hearing device according to Claim 10 wherein said supports are constructed and arranged to move independently of each other.
15. A self-expanding hearing device according to Claim 10 wherein said supports are springs.
16. A self-expanding hearing device according to Claim 15 wherein said springs are constructed of metal.
17. A self-expanding hearing device according to Claim 16 wherein said springs are constructed of Nitinol.
18. A self-expanding hearing device according to Claim 16 wherein said springs are constructed of Elgiloy.
19. A self-expanding hearing device according to Claim 16 wherein said springs are constructed of spring steel.
20. A self-expanding hearing device according to Claim 16 wherein said springs are constructed of MP35 alloy.

21. A self-expanding hearing device according to Claim 10 wherein said supports are shaped in a spiral configuration.

22. A self-expanding hearing device according to Claim 10 wherein said supports are shaped in a mesh configuration.

23. A self-expanding hearing device according to Claim 10 wherein said supports are 0.002 to 0.02 inches wide.

24. A self-expanding hearing device according to Claim 23 wherein said supports are 0.004 to 0.015 inches wide.

25. A self-expanding hearing device according to Claim 24 wherein said supports are 0.005 to 0.01 inches wide.

26. A self-expanding hearing device according to Claim 10 wherein said supports are formed of a shape memory material.

27. A self-expanding hearing device according to Claim 26 wherein said shape memory material is Nitinol.

28. A self-expanding hearing device according to Claim 27 wherein said shape memory material is Nitinol with material activation temperature between 20°C and 40°C.

29. A self-expanding hearing device according to Claim 10 wherein said supports expand from a compressed, undeployed state to a deployed state when warmed above the material activation temperature.
30. A self-expanding hearing device according to Claim 29 wherein the material activation temperature is about 20°C.
31. A self-expanding hearing device according to Claim 29 wherein the material activation temperature is above 25°C and below 37°C.
32. A self-expanding hearing device according to Claim 1 wherein said membrane encloses said frame.
33. A self-expanding hearing device according to Claim 1 wherein said membrane partially encloses said frame.
34. A self-expanding hearing device according to Claim 1 further comprising a sealing fin connected to said membrane.
35. A self-expanding hearing device according to Claim 1 wherein said membrane is constructed from elastic material.

36. A self-expanding hearing device according to Claim 1 wherein said membrane is constructed from inelastic material.

37. A self-expanding hearing device according to Claim 1 wherein said membrane is 0.00025 to 0.2 inches thick.

38. A self-expanding hearing device according to Claim 37 wherein said membrane is 0.0005 to 0.05 inches thick.

39. A self-expanding hearing device according to Claim 38 wherein said membrane is 0.001 to 0.025 inches thick.

40. A self-expanding hearing device according to Claim 1 wherein said membrane comprises at least two zones, and said membrane has a first thickness in the first zone and a second thickness in the second zone.

41. A self-expanding hearing device according to Claim 40 wherein the first thickness is smaller than the second thickness.

42. A self-expanding hearing device according to Claim 40 wherein the first thickness is between 0.00025 and 0.02 inches.

43. A self-expanding hearing device according to Claim 40 wherein the second thickness is between 0.02 and 0.2 inches.
44. A self-expanding hearing device according to Claim 1 wherein said membrane is coupled to said frame.
45. A self-expanding hearing device according to Claim 1 wherein said membrane is not coupled to said frame.
46. A self-expanding hearing device according to Claim 10 wherein said body has a proximal end and a distal end and said supports are connected to said body by a proximal connector and a distal connector.
47. A self-expanding hearing device according to Claim 46 wherein said proximal connector is constructed and arranged to move relative to said body when the user compresses said frame.
48. A self-expanding hearing device according to Claim 46 wherein said distal connector is constructed and arranged to move relative to said body when the user compresses said frame.
49. A self-expanding hearing device according to Claim 1 wherein said frame is comprised of plurality of sections.

50. A self-expanding hearing device according to Claim 49 wherein said frame is comprised of a proximal section, a distal section and a middle section.
51. A self-expanding hearing device according to Claim 50 wherein at least two of said sections are substantially different in configuration from each other.
52. A self-expanding hearing device comprising:  
a body,  
a frame coupled to said body, said frame being constructed so that a user can compress said frame for insertion into the user's ear canal and when the user releases the compression the frame expands; and,  
a membrane coupled to said body, wherein said membrane is constructed to enclose said frame and to control the rate of expansion of said frame.
53. A self-expanding hearing device according to Claim 52 wherein said membrane is comprised of a material which is permeable to air and the rate of permeability is selectable.
54. A self-expanding hearing device according to Claim 52 wherein membrane is comprised of a material which is not permeable to air, and the device further comprises air inlet means to allow air to enter said membrane at a controllable rate.



55. A self-expanding hearing device comprising:  
a body; and,  
a frame coupled to said body, said frame being constructed so that a user can  
compress said frame for insertion into the user's ear canal and when the  
user releases the compression the frame expands.
56. A self-expanding hearing device according to Claim 55 wherein said body  
includes a microphone and a speaker.
57. A self-expanding hearing device according to Claim 55 wherein said body is  
flexible.
58. A self-expanding hearing device according to Claim 55 wherein said frame  
includes a plurality of supports.
59. A self-expanding hearing device according to Claim 58 wherein said supports are  
elastic.
60. A self-expanding hearing device according to Claim 58 wherein said supports are  
formed of a superelastic material.
61. A self-expanding hearing device according to Claim 60 wherein said superelastic  
material is Nitinol.

62. A self-expanding hearing device according to Claim 58 wherein said supports are constructed and arranged to move independently of each other.

63. A self-expanding hearing device according to Claim 58 wherein said supports are shaped in a spiral configuration.

64. A self-expanding hearing device according to Claim 58 wherein said body has a proximal end and a distal end and said supports are connected to said body by a proximal connector and a distal connector.

65. A self-expanding hearing device according to Claim 64 wherein said proximal connector is constructed and arranged to move relative to said body when the user compresses said frame.

66. A self-expanding hearing device according to Claim 64 wherein said distal connector is constructed and arranged to move relative to said body when the user compresses said frame.

67. A kit for a balloon-expandable hearing device fitting system, the kit comprising:  
an occlusion wire;  
a balloon expander;  
ear gel; and,

a hearing aid.

68. A method for installing a hearing aid in a patient's ear canal, the method comprising:

- inserting an occlusion wire into a patient's ear canal;
- inflating a bulb at the end of the occlusion wire to occlude the ear canal;
- filling the patient's ear canal with ear gel;
- placing a balloon expander over the occlusion wire;
- inserting the balloon expander within the ear gel;
- expanding the balloon to form a cavity in the ear gel;
- deflating the balloon;
- removing the balloon from the ear canal;
- removing the occlusion wire from the ear canal; and
- installing the hearing aid in the cavity in the ear gel.

69. A method of installing a hearing aid device into an ear canal, comprising the steps of:

- inserting an occlusion wire into the ear canal' the occlusion wire;
- inflating a soft-tip bulb;
- filling the ear canal with ear gel;
- inserting a balloon expander;
- inflating the balloon expander;

removing the balloon expander and hearing aid shell; and  
preparing and inserting the hearing aid device into the ear canal.

70. Method of installing a hearing aid device, comprising the steps of:

Insert an Occlusion Wire into the ear canal' the occlusion wire, including:  
a semi-rigid plastic or metal wire approximately 3 inches in length with  
a small (1 mm) lumen running the length of the wire through the center;  
at the distal end of the wire is a soft-tip, inflatable bulb;  
the wire is slight bent to the curvature of the ear canal and then inserted into the  
ear approximately 2/3 the length of the ear canal;

inflating the soft-tip bulb, having the steps of:  
using a syringe filled with saline solution, the hearing care professional (HCP)  
slowly inflates the soft tip bulb to completely occlude the ear canal having the  
bulb takes the shape of the ear canal but can expand to a maximum diameter of 9-  
10 mm;  
stopping inflating when a patient feels pressure and 'fullness' sensation in the ear  
once the bulb is fully-inflated; and  
temporarily sealing a proximal end of the occlusion wire to keep the bulb  
inflated;

filling ear canal with an ear gel, including the steps of:

filling the ear canal with liquid ear gel, with patient's head turned to the side;

applying, the ear gel from small bottle or syringe; and

curing the ear gel to semi-soft condition within 15-20 minutes and fully curing overnight to a permanent shell,

wherein the ear gel may cure when exposed to heat (body temperature), air or when mixed with a chemical catalyst; and

wherein the ear gel comprises a material is some derivative of medical grade silicone with minimal shrinkage;

inserting a balloon expander, including the steps of:

designing the balloon expander to be a flexible metal or plastic-based wire with dual lumens in the center of the wire;

wherein, one lumen is used to track the expander over the occlusion wire; and

wherein a second lumen is used to inflate the balloon once in the ear canal;

designing the balloon portion to be about 15-18 mm in length and has a tapered expansion from about 6.5- 7.5 mm in diameter;

inflating the balloon using saline solution injected via syringe; the quantity of saline injected helps determine the size of balloon inflation; and

placing the balloon expander over the occlusion wire and gently inserted within the ear gel up to the soft-tip bulb;

inflating the balloon expander, having the following steps:

creating a 'pocket' for the hearing aid by inflating the balloon to a pre-designated

size corresponding to the the size of the hearing aid;

wherein hearing aid size is determined by either or both of the level of balloon

compliance and/or amount of saline injected via syringe into the balloon;

designing the balloon to be highly lubricious to prevent adhesion to ear gel;

maintaining the balloon in place during ear gel 'cure';

removing the balloon expander and hearing aid shell, having steps of:

withdrawing saline solution back into the syringe to deflate the balloon expander

and remove from the ear; and

pulling back the occlusion wire and shell from the ear canal; and

preparing and inserting hearing aid, having steps of:

trimming proximal edges and cut distal end of the shell with scissors;

inserting the hearing aid into custom shell;

placing the hearing aid and custom shell into ear canal; and

programming the device, as necessary.